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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,712	08/31/2001	Takafumi Kohama	00626A/HG	1333

1933 7590 12/13/2002

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NEW YORK, NY 10017-2023

EXAMINER
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JONES, DWAYNE C

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 12/13/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/943,712

Applicant(s)

KOHAMA ET AL.

Examiner

Dwayne C Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Status of Claims*

1. Claims 1-28 are pending.
2. Claims 1-28 are rejected.

### *Response to Arguments*

3. Applicant's arguments filed September 30, 2002 have been fully considered but they are not persuasive. Applicants argue that Kamiya et al. only teach of various ACAT inhibitors whereas the instant invention is directed to the ACAT inhibitor of N-(1-Octyl-5-carboxymethyl-4,6-dimethylindolin-7-yl)-2,2-dimethylpropanamide along.

4. This allegation is not found persuasive because Kamiya et al. teach of the treatment of arteriosclerosis, hyperlipemia, and cardiovascular ischemic disease with the compound N-(1-Octyl-5-carboxymethyl-4,6-dimethylindolin-7-yl)-2,2-dimethylpropanamide, (see Example 4). In fact, in claim 16 Kamiya et al. recite only six ACAT inhibiting compounds. Moreover, Kamiya et al. list teach the compound N-(1-Octyl-5-carboxymethyl-4,6-dimethylindolin-7-yl)-2,2-dimethylpropanamide as an example of the *most preferable compound*, (see column 6, lines 37 and 41-43). For these reasons, one having ordinary skill in the art is motivated to utilize the most preferable compounds as ACAT inhibitors, especially when Kamiya et al. recite the very same compound, as applicants, in claim 16 only with five other ACAT inhibiting compounds.

***Information Disclosure Statement***

5. The information disclosure statement filed on September 30, 2002 have been reviewed and considered, see enclosed copies of PTO FORM1449.

***Claim Rejections - 35 USC § 103***

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. The rejection of claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bocan of WO 97/16184 in view of Kamiya et al. of EP 866,059 A1 is maintained and repeated. Bocan teaches of the combination of inhibitors of acyl-CoA: cholesterol acyltransferase, (ACAT) inhibitors and HMG-CoA-reductase inhibitors. Bocan also teach that these compounds are known to lower LDL cholesterol as well as treating atherosclerotic disease, (see abstract and pages 1-3). In fact, Bocan specifically teaches of the following HMG-CoA-reductase inhibitors of atorvastatin, lovastatin, simvastatin, pravastatin and fluvastatin, (see pages 3 and 4). Kamiya et al. teach of inhibitors of acyl-CoA: cholesterol acyltransferase, (see abstract and page 1). In particular, Kamiya et al. teach of the treatment of arteriosclerosis, hyperlipemia, and cardiovascular ischemic disease with the compound N-(1-Octyl-5-carboxymethyl-4,6-dimethylindolin-7-yl)-2,2-dimethylpropanamide, (see Example 4). Since both of these prior art references are directed to treating the very same ailment it the skilled artisan would have been motivated to substitute one ACAT inhibitor for another. In addition,

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the ACAT inhibitors of Kamiya et al. possess improved oral absorptions, strong anti-hyperlipemia and anti-arteriosclerosis effects, (see page 1, lines 50-55).

### ***Conclusion***

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

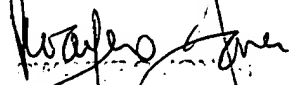
Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1235.

  
Tech. Ctr. 1614

December 12, 2002